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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/669,591 | 09/24/2003 | Doug Duchon | 57173/1481 | 5690 |
| 7590 | 09/03/2008 | | EXAMINER | |
| Kramer Levin Naftalis & Frankel LLP 1177 Avenue of the Americas New York, NY 10036 | | WITCZAK, CATHERINE | | |
| | | ART UNIT | | PAPER NUMBER |
| | | 3767 | | |
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| | | 09/03/2008 | | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/669,591 | DUCHON ET AL. | |
| | Examiner | Art Unit | |
| | CATHERINE N. WITCZAK | 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 March 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 23-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23-37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 23-25, 27, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al (US Patent No. 4596575).

Rosenberg et al discloses an injection device which automatically refills a syringe, the method comprising sensing a volume of fluid in a chamber of the syringe, receiving a preset amount of fluid necessary for a subsequent injection from user input; comparing said volume in said chamber with said preset amount of fluid and retracting a plunger within said chamber of said syringe to a predetermined limit if said preset amount of fluid is greater than the volume of fluid sensed in said chamber, wherein predetermined limit maximally fills said chamber of said syringe, wherein the predetermined limit is less than a maximal volume of said chamber, see col. 1 line 60 - col. 2 line 5, col. 2 line 66 - col. 3 line 7, col. 5 line 65 - col. 6 line 17.

2. Claims 23-27 & 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Degironimo et al (US Patent No. 4502488).

Degironimo discloses an injection device which automatically refills a syringe, the method comprising sensing a volume of fluid in a chamber of the syringe, receiving a preset amount of fluid necessary for a subsequent injection from user input; comparing said volume in said chamber with said

preset amount of fluid and retracting a plunger within said chamber of said syringe to a predetermined limit if said preset amount of fluid is greater than the volume of fluid sensed in said chamber, wherein predetermined limit maximally fills said chamber of said syringe, wherein the predetermined limit is less than a maximal volume of said chamber, and wherein the preset amount of fluid can be changed, see col. 2 line 10-15 & lines 39-54.

With respect to claim 26, wherein the reference discloses the step of purging air bubbles, see col. 5 line 66 - col. 6 line 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al (US Patent No. 4596575) in view of Reinicke (US Patent No. 4684365).

Even though Rosenberg does not explicitly state the step of purging air from the chamber of the syringe attention is directed to Reinicke. The Reinicke reference teaches the step of purging air from the chamber of the syringe col. 7 line 47-51. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the air purging step of Reinicke into the method of Rosenberg in order to provide a safer device and to allow for a faster refill.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Degironimo et al (US Patent No. 4502488) as applied to claim 23 and further in view of Rubinstein (US Patent No. 3888239).

Now even though Degironimo does not explicitly disclose the injection of radiographic contrast material attention is directed to Rubinstein. The Rubenstein reference teaches the use of an injector that is capable of injecting multiple different materials including that of delivering contrast material in order to perform angiographic procedures. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Rubenstein by utilizing the injector of Degironimo to deliver any fluid necessary for the procedure.

5. Claims 32-37 are rejected as being unpatentable over Rosenberg OR Degironimo as applied above, in further view of Riley et al (US 5,672,155).

Rosenberg OR Degironimo disclose the claimed invention except for the plunger being retracted at a first, slower speed of about 2mL/sec until about 40mL of fluid has been withdrawn, followed by a faster rate of 3mL/sec. Riley teaches in column 12, lines 12-36 that it is known to use an initial slow rate of retraction.. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to start with a slow retraction speed as taught by Riley et al in the method of Rosenberg OR Degironimo in order to prevent air from being drawn in. [Furthermore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the speed from a slower rate of 2mL to a faster retraction rate of about 3mL because Applicant has not disclosed that these particular rates (ie 2mL/sec and 3mL/sec) provide an advantage, is used for a particular purpose, or solves a stated problem.

Response to Arguments

Applicant's arguments filed 5/8/2008 have been fully considered but they are not persuasive. Applicant argues that Rosenberg and Degironomo do not teach the invention as currently claimed. Examiner disagrees. In the case of Rosenberg, the "user input associated with a subsequent injection" is

considered to be the user's decision to start infusion by activating the start button. As to arguments regarding Rosenberg and Degironimo not teaching the limitation "determining a preset amount of fluid necessary for the subsequent injection based on the user input," Examiner contends that there is nothing preventing the subsequent injection volume from being the same as the injection volume - with the case being that the entire volume is expelled from the syringe - in which case at the end of the injection, the volume in the chamber is zero and the amount that is determined needs to be refilled is exactly the same as the previous volume.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767